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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,013

03/16/2004

Gary M. Kawesch

KAWESCH-002XX

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7590

02/22/2007

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EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/803,013

Applicant(s)

KAWESCH, GARY M.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 17-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claim 16 in the reply filed on January 31, 2007 is acknowledged.

Election/Restrictions

2. Applicant's election without traverse of Invention/Group I (claims 1-23, drawn to a corneal inlay) in the reply filed on January 31, 2007 is acknowledged.
3. Applicant's election without traverse of the corneal inlay embodied in claim 1 (species A) in the reply filed on January 31, 2007 is acknowledged. Species B (embodied in claim 17) and Species C (embodied in claim 20) are withdrawn from further consideration.
4. Claims 17-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/group and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 31, 2007. It should be noted that the Applicant did not make an election on a SINGLE species of the "CORNEAL INLAY SPECIES" listed in pages 3 and 4 of the Restriction and Election of Species requirement mailed on November 2, 2006. Those embodiments/species are clearly represented in dependent claims 2-16.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the protrusion as including: (i) a generally arc shape, (ii) a ring shape, (iii) a non-circular outer

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perimeter, as described in the specification. In addition, from the Figures it is difficult to distinguish between the corneal flap, the corneal inlay, the embodiments/species of the protrusion, and the aperture inside the corneal tissue. Further, it is difficult to distinguish what delimits the structural features represented by characters 10, 12, 14, and 22.

6. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 4, 7-10, 12, and 15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Peyman (US 5,919,185 A).

Referring to Figures 46-59, Peyman discloses a corneal inlay (60) comprising a top surface (63) and at least a bottom surface (65), wherein said bottom surface includes at least one protrusion (small portion 64) extending downwardly, wherein said protrusion is *sized and shaped to fit* within at least one aperture (**first aperture**: ablated section 71; **second aperture**: ablated section 70) disposed in said cornea. Said at least one protrusion (small portion 64) is straight and generally cylindrical. Peyman discloses that the at least one protrusion (small portion 64) does not have to be circular, but that it could be oval-shaped, rectangular-shaped, or may comprise other shapes (see column 13, lines 52-59). In addition, bottom surface 65 may comprise other projected portions, such as texture (i.e., “microscopic spike like protrusions”; see column 13, lines 65-67). The size and shape of the at least one projection is shaped to fit the size and shape of the aperture (see column 14, lines 40-46).

NOTE: With regards to the functional limitations “*adapted to engage*” and “*sized and shaped to fit*”, claims directed to apparatus must be distinguished from the prior art in terms of structure

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rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v.*

Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

9. Claims 1, 3, 7, 9, 11, 15, and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by N.O. Stimson (US 2,653,515).

Referring to Figures 1-12, N.O. Stimson discloses a corneal implant comprising a top surface and at least a bottom surface, wherein said bottom surface includes at least one protrusion (facets or protuberances 18) extending downwardly, wherein said protrusion is *sized and shaped to fit* within at least one aperture disposed in said cornea. Said at least one protrusion is straight, and offset from the center of said corneal implant. The implant may comprise one protuberance/facet 18 (see Figure 10), or more than one protuberance/facet 18. The size and shape of the at least one projection is shaped to fit the size and shape of an aperture.

NOTE: If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).

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NOTE: With regards to the functional limitations “*adapted to engage*” and “*sized and shaped to fit*”, claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

10. Claims 1, 4-7, 9, and 12-15 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by White (US 6,755,858 B1).

Referring to Figures 8-11, White discloses a corneal inlay (10) comprising a top surface and at least a bottom surface (**first interpretation:** bottom surface of dome-shaped head 20; **second interpretation:** bottom surface of stem 14; **third interpretation:** surface 26, which is lower than dome-shaped head 20; **fourth interpretation:** bottom surface of dome-shaped head 20 + surface 26 + bottom surface of stem 14), wherein said bottom surface includes at least one protrusion (**first interpretation:** stem 14; **second interpretation:** ring 40; **third interpretation:** stem 14 + ring 40) extending downwardly, wherein said protrusion is *sized and shaped to fit* within at least one aperture (**first interpretation:** bore 32; **second interpretation:** bore where ring 40 is going to rest; **third interpretation:** bore 32 + bore where ring 40 is going to rest) disposed in said cornea. Said at least one protrusion is straight and generally cylindrical (e.g., stem 14). Alternatively, said at least one protrusion is annular/ring-shaped or arc shaped (e.g.,

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ring 40). The size and shape of the at least one projection is *shaped to fit* the size and shape of the aperture.

NOTE: With regards to the functional limitations “*adapted to engage*” and “*sized and shaped to fit*”, claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 3, 5, 6, 11, 13, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,919,185 A).

Peyman discloses the invention as claimed in claims 1, 2, 4, 7-10, 12, and 15. Although Peyman discloses that the at least one protrusion (small portion 64) does not have to be circular, but that it could be oval-shaped, rectangular-shaped, or may comprise other shapes (see column 13, lines 52-59), he/she does not particularly disclose the protrusion species claimed in claims 3,

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5, 6, 11, 13, 14, and 16. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have modified Peymans's corneal inlay to have any of the protrusion species claimed in claims 3, 5, 6, 11, 13, 14, and 16 because the Applicant have not disclosed that having said shapes provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with ANY of the protrusion species claimed in claims 3, 5, 6, 11, 13, 14, and 16 because those shapes would have equally permitted the corneal inlay to be securely attached to the cornea, while preventing movement and/or detachment of said corneal inlay.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco



February 7, 2007


David H. Willse
Primary Examiner